

**Technical Project Lead (TPL) Review:**

**SE0002197, SE0002204, SE0002206, SE0002218,
SE0002219, SE0002224, SE0002228 – SE0002230,
SE0002235, SE0002240 – SE0002242, SE0002246,
SE0002250, SE0002252 – SE0002255, SE0002257**

SE0002197: Beretta Extreme King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002204: Fresh Choice Full Flavor King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002206: Royal Majestic Red King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002218: Beretta Elite King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None

TPL Review for SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228 – SE0002230, SE0002235, SE0002240 – SE0002242, SE0002246, SE0002250, SE0002252 – SE0002255, SE0002257

SE0002219: Beretta Silver King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002224: Royal Majestic Blue King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002228: Beretta Original 100mm	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002229: Ramback Prestige 100mm	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002230: Windsail Prestige 100mm	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None

SE0002235: Royal Majestic Red 100s	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002240: Beretta Elite 100mm	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002241: Ramback Elite 100mm	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002242: Windsail Elite 100mm	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002246: Royal Majestic Blue 100s	
Package Type	Box
Package Size	200 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None

TPL Review for SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228 – SE0002230, SE0002235, SE0002240 – SE0002242, SE0002246, SE0002250, SE0002252 – SE0002255, SE0002257

SE0002250: Cheap Tobacco King Size (Green Box)	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0002252: Beretta Menthol King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0002253: Wingate Menthol King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0002254: Shargio Green Cigarette Tubes King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0002255: Fresh Choice Menthol King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None

TPL Review for SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228 – SE0002230, SE0002235, SE0002240 – SE0002242, SE0002246, SE0002250, SE0002252 – SE0002255, SE0002257

SE0002257: Royal Majestic Green King Size	
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
Common Attributes of SE Reports	
Applicant	Silverfoiltubes International, Inc.
Report Type	Regular
Product Category	Roll-Your-Own Tobacco
Product Sub-Category	Filtered Cigarette Tube
Recommendation	
Issue Substantially Equivalent (SE) orders.	

Technical Project Lead (TPL):

Digitally signed by Matthew R. Holman -S
Date: 2015.04.10 07:11:09 -04'00'

Matthew R. Holman, Ph.D.
Director
Division of Product Science

Signatory Decision:

- ☒ Concur with TPL recommendation and basis of recommendation
- ☐ Concur with TPL recommendation with additional comments (see separate memo)
- ☐ Do not concur with TPL recommendation (see separate memo)

Digitally signed by David Ashley -S
Date: 2015.04.10 07:20:01 -04'00'

David L. Ashley, Ph.D.
RADM, U.S. Public Health Service
Director
Office of Science

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1. BACKGROUND

1.1. PREDICATE TOBACCO PRODUCTS

The applicant submitted the following predicate tobacco products:

SE0002197: Beretta Extreme King Size	
Product Name	Zen Full Flavor Cigarette Tubes King Size
Package Type	Box
Package Size	250 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002204: Fresh Choice Full Flavor King Size	
Product Name	Zen Full Flavor Cigarette Tubes King Size
Package Type	Box
Package Size	250 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002206: Royal Majestic Red King Size	
Product Name	Zen Full Flavor Cigarette Tubes King Size
Package Type	Box
Package Size	250 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002218: Beretta Elite King Size	
Product Name	Zen Light Cigarette Tubes King Size
Package Type	Box
Package Size	250 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None

SE0002219: Beretta Silver King Size	
Product Name	Zen Light Cigarette Tubes King Size
Package Type	Box
Package Size	250 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002224: Royal Majestic Blue King Size	
Product Name	Zen Light Cigarette Tubes King Size
Package Type	Box
Package Size	250 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002228: Beretta Original 100mm	
Product Name	Zen Full Flavor Cigarette Tubes 100mm
Package Type	Box
Package Size	250 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002229: Ramback Prestige 100mm	
Product Name	Zen Full Flavor Cigarette Tubes 100mm
Package Type	Box
Package Size	250 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None

TPL Review for SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228 – SE0002230, SE0002235, SE0002240 – SE0002242, SE0002246, SE0002250, SE0002252 – SE0002255, SE0002257

SE0002230: Windsail Prestige 100mm	
Product Name	Zen Full Flavor Cigarette Tubes 100mm
Package Type	Box
Package Size	250 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002235: Royal Majestic Red 100s	
Product Name	Zen Full Flavor Cigarette Tubes 100mm
Package Type	Box
Package Size	250 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002240: Beretta Elite 100mm	
Product Name	Zen Light Cigarette Tubes 100mm
Package Type	Box
Package Size	250 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002241: Ramback Elite 100mm	
Product Name	Zen Light Cigarette Tubes 100mm
Package Type	Box
Package Size	250 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None

SE0002242: Windsail Elite 100mm	
Product Name	Zen Light Cigarette Tubes 100mm
Package Type	Box
Package Size	250 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002246: Royal Majestic Blue 100's	
Product Name	Zen Light Cigarette Tubes 100mm
Package Type	Box
Package Size	250 tubes
Length	100 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	None
Additional Property	None
SE0002250: Cheap Tobacco King Size (green box)	
Product Name	Zen Menthol Cigarette Tubes King Size
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0002252: Beretta Menthol King Size	
Product Name	Zen Menthol Cigarette Tubes King Size
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None

SE0002253: Wingate Menthol King Size	
Product Name	Zen Menthol Cigarette Tubes King Size
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0002254: Shargio Green Cigarette Tubes King Size	
Product Name	Zen Menthol Cigarette Tubes King Size
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0002255: Fresh Choice Menthol King Size	
Product Name	Zen Menthol Cigarette Tubes King Size
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None
SE0002257: Royal Majestic Green King Size	
Product Name	Zen Menthol Cigarette Tubes King Size
Package Type	Box
Package Size	200 tubes
Length	84 mm
Diameter	8.1 mm
Filter Ventilation	None
Characterizing Flavor	Menthol
Additional Property	None

The predicate tobacco products are filtered cigarette tubes manufactured by the applicant.

1.2. REGULATORY ACTIVITY RELATED TO THIS REVIEW

The applicant submitted the 20 SE Reports on March 16, 2011. It should be noted that these SE Reports were originally classified by FDA as provisional SE Reports. Section 910(a)(2)(B) of the FD&C Act includes the following requirements for an SE Report to be classified as provisional:

1. The SE Report is submitted to FDA by March 22, 2011.
2. The new tobacco product was “was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States” between February 16, 2007, and March 21, 2011.

Because these SE Reports were classified as provisional SE Reports, Public Health Impact (PHI) reviews were filed on December 6, 2012. In June 2013, the applicant submitted amendments to these SE Reports which, among other things, notified FDA that they had not yet commercially marketed the new tobacco products in the United States. Therefore, these SE Reports were reclassified by FDA as regular SE Reports because they do not meet the second requirement in section 910(a)(2)(B) of the FD&C Act.

FDA sent the applicant administrative Advice/Information (A/I) Request letters in May 2013¹ and in June 2013². In response to the administrative A/I letters, the applicant amended all of the SE Reports in June 2013. FDA sent the applicant a scientific A/I letter covering all of the SE Reports in October 2014. The applicant responded to the scientific A/I letter in November 2014 (SE0010768) and in December 2014 (SE0010776 and SE0010788).

¹ SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228 - SE0002230, SE0002235, and SE0002240 – SE0002242

² SE0002246, SE0002250, SE0002252 – SE0002255, and SE0002257

TPL Review for SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228 – SE0002230, SE0002235, SE0002240 – SE0002242, SE0002246, SE0002250, SE0002252 – SE0002255, SE0002257

Product Name	SE Report	Amendments
Beretta Extreme King Size	SE0002197	SE0009065 SE0010768 SE0010776 SE0010788
Fresh Choice Full Flavor King Size	SE0002204	SE0009089 SE0010768 SE0010776 SE0010788
Royal Majestic Red King Size	SE0002206	SE0009091 SE0010768 SE0010776 SE0010788
Beretta Elite King Size	SE0002218	SE0009111 SE0010768 SE0010776 SE0010788
Beretta Silver King Size	SE0002219	SE0009111 SE0010768 SE0010776 SE0010788
Royal Majestic Blue King Size	SE0002224	SE0009111 SE0010768 SE0010776 SE0010788
Beretta Original 100mm	SE0002228	SE0009111 SE0010768 SE0010776 SE0010788
Ramback Prestige 100mm	SE0002229	SE0009111 SE0010768 SE0010776 SE0010788
Windsail Prestige 100mm	SE0002230	SE0009111 SE0010768 SE0010776 SE0010788
Royal Majestic Red 100s	SE0002235	SE0009111 SE0010768 SE0010776 SE0010788
Beretta Elite 100mm	SE0002240	SE0009111 SE0010768 SE0010776 SE0010788

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Product Name	SE Report	Amendments
Ramback Elite 100mm	SE0002241	SE0009111 SE0010768 SE0010776 SE0010788
Windsail Elite 100mm	SE0002242	SE0009111 SE0010768 SE0010776 SE0010788
Royal Majestic Blue 100s	SE0002246	SE0009151 SE0010768 SE0010776 SE0010788
Cheap Tobacco King Size (green box)	SE0002250	SE0009151 SE0010768 SE0010776 SE0010788
Beretta Menthol King Size	SE0002252	SE0009151 SE0010768 SE0010776 SE0010788
Wingate Menthol King Size	SE0002253	SE0009151 SE0010768 SE0010776 SE0010788
Shargio Green Cigarette Tubes King Size	SE0002254	SE0009151 SE0010768 SE0010776 SE0010788
Fresh Choice Menthol King Size	SE0002255	SE0009151 SE0010768 SE0010776 SE0010788
Royal Majestic Green King Size	SE0002257	SE0009151 SE0010768 SE0010776 SE0010788

1.3. SCOPE OF REVIEW

This memo captures all administrative, compliance, and scientific reviews completed for these SE Reports.

2. ADMINISTRATIVE REVIEW

A first round of administrative completeness reviews was completed by Tiffany Petty on May 21, 2013, May 30, 2013, and June 4, 2013. A second round of administrative completeness reviews was completed by Shireen Ahmad on September 20, 2013, September 26, 2013, October 8, 2013, October 11, 2013, October 21, 2013, October 30, 2013, and January 2, 2014.

The final completeness review concludes that the SE Reports are not administratively complete because the SE Reports did not include the “basis for the submitter’s determination that the new tobacco products are substantially equivalent (e.g., state same characteristics or different characteristics that do not raise new questions of public health).” However, in amendments SE0009065, SE0009089, SE0009091, SE0009111, SE0009151, and SE0010547, the applicant states that it believes the characteristics of the new and corresponding predicate tobacco products to be the same. Therefore, these SE Reports are administratively complete.

3. COMPLIANCE REVIEW

The Office of Compliance and Enforcement (OCE) completed reviews to determine whether the applicant established that the predicate tobacco products are grandfathered products (i.e., were commercially marketed as of February 15, 2007). The OCE reviews dated April 24, 2014³, April 28, 2014⁴, April 30, 2014⁵, and June 6, 2014⁶, conclude that the evidence submitted by the applicant is adequate to demonstrate that the predicate tobacco products are eligible predicate tobacco products.

The Office of Compliance and Enforcement (OCE) also completed a review to determine whether the new tobacco products are in compliance with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as required by section 905(j)(1)(A)(i) of the FD&C Act. The OCE review dated March 17, 2015, concludes that the new tobacco products are in compliance with the FD&C Act.

³ SE0002228-SE0002230, SE0002235

⁴ SE0002197, SE0002206, SE0002218, SE0002219, SE0002224, SE0002240 – SE0002242, SE0002246

⁵ SE0002250, SE0002252 – SE0002255, SE0002257. It should be noted that the April 30, 2014, reviews do not include the length of the predicate tobacco products, but the stand-alone grandfather submissions referenced in the reviews include the lengths of the predicate tobacco products. Because the stand-alone grandfather submissions are incorporated into the April 30, 2014, reviews, the lengths of the predicate tobacco products have been identified.

⁶ SE0002204

4. SCIENTIFIC REVIEW

Scientific reviews were completed by the Office of Science (OS) for the following disciplines⁷:

4.1. CHEMISTRY

Chemistry reviews were completed by Zhong Li on July 18, 2014, and by Tricia Johnson on January 26, 2015.

The final chemistry review concludes that the new tobacco products have the following key difference compared to the corresponding predicate tobacco products:

- Product quantity changed from 200 filtered cigarette tubes per box to 250 filtered cigarette tubes per box for SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228—SE0002230, SE0002235, SE0002240, SE0002241, SE0002242 and SE0002246.⁸

The product quantity for the new and predicate tobacco products in SE0002250, SE0002252-SE0002255, and SE0002257 is 200 filtered cigarette tubes per box. The packaging materials used in the new and predicate tobacco products are identical. Therefore, the chemistry review concludes that the new tobacco products do not raise different questions of public health.

4.2. ENGINEERING

Engineering reviews were completed by Ryan Foringer and Tiffany Petty on July 23, 2014, and by Tiffany Petty on January 14, 2015.

The final engineering review concludes that the new tobacco products have the following key differences compared to the predicate tobacco products:

- Product quantity and brand name

The applicant provided adequate information to demonstrate that the change in product quantity does not cause the new tobacco product to raise different questions of public health from a product engineering standpoint. The engineering review did not evaluate the label (brand name).

⁷ A toxicology review was not completed because the composition and design characteristics were determined to be the same for the new and corresponding predicate tobacco products.

⁸ It should be noted that the package quantity change was actually a decrease from 250 to 200 filtered cigarette tubes per box.

4.3. SOCIAL SCIENCE

A social science review was completed by Katherine A. Margolis on February 17, 2015.

The social science review concludes that the new tobacco products in SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228—SE0002230, SE0002235, SE0002240 – SE0002242, and SE0002246 have different characteristics than the predicate tobacco products due to a decrease in product quantity from 250 cigarette tubes per box to 200 cigarette tubes per box. However, the social science review concludes that there is no available scientific evidence on the influence that the number of cigarette tubes per box has on consumer perceptions or use intentions to indicate that such a decrease from 250 to 200 would cause the new tobacco products to raise different questions of public health from a social science perspective.

5. ENVIRONMENTAL DECISION

A finding of no significant impact (FONSI) was signed by Kimberly Benson, Ph.D. on April 3, 2015. The FONSI was supported by an environmental assessment prepared by FDA on April 3, 2015.

6. CONCLUSION AND RECOMMENDATION

The following is the only difference in characteristics between the new and predicate tobacco products:

- Number of tubes per package decreased from 250 to 200 in SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228—SE0002230, SE0002235, SE0002240 – SE0002242, and SE0002246

The product characteristics of the new and corresponding tobacco predicate products in SE0002250, SE0002252-SE0002255, and SE0002257 are the same. In all SE Reports, the product names differ between the new and corresponding predicate tobacco products.

The applicant has adequately demonstrated that the change in product quantity does not cause the new tobacco products to raise different questions of public health. The applicant explains the difference in product quantity is due (b) (4)

Furthermore, the social science review states that there is no available scientific evidence regarding the influence that this difference in the number of cigarette tubes per box has on consumer perceptions or use intentions to indicate that such a decrease of 250 to

TPL Review for SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228 – SE0002230, SE0002235, SE0002240 – SE0002242, SE0002246, SE0002250, SE0002252 – SE0002255, SE0002257

200 would cause the new tobacco products to raise different questions of public health. Therefore, the differences in product quantity between the new and corresponding predicate tobacco products in SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228—SE0002230, SE0002235, SE0002240 – SE0002242, and SE0002246 does not cause the new tobacco products to raise different questions of public health.

The predicate tobacco products meet statutory requirements because they are grandfathered products (i.e., were commercially marketed in the United States as of February 15, 2007).

The new tobacco products are currently in compliance with the FD&C Act. In addition, all of the scientific reviews conclude that the differences between the new and corresponding predicate tobacco products are such that the new tobacco products do not raise different questions of public health. I concur with these reviews and recommend that SE order letters be issued.

FDA has examined the environmental effects of finding these new tobacco products substantially equivalent and made a finding of no significant impact.

SE order letters should be issued for the new tobacco products in SE0002197, SE0002204, SE0002206, SE0002218, SE0002219, SE0002224, SE0002228 – SE0002230, SE0002235, SE0002240 – SE0002242, SE0002246, SE0002250, SE0002252 – SE0002255, and SE0002257, as identified on the cover page of this review.